IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/065,278	Confirmation No.: 5691
Applicant	:	Leung et al.	
Filed	:	September 30, 2002	
Art Unit	:	3731	
Examiner	:	Glenn Dawson	
Docket No.	:	013341-000021	
Customer No.	:	24,239	

For : Barbed Suture in Combination with Surgical Needle

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

DECLARATION OF DR. GREGORY L. RUFF

I, Dr. Gregory L. Ruff, declare as follows:

1. I am a United States citizen and my domicile address is 113 Campbell Lane, Chapel Hill, NC 27514.

2. I am an inventor on several patents and pending patent applications describing barbed tissue connectors and sutures, along with their uses. A list of these patents and published pending applications is set forth in Exhibit A.

3. I received an M.D. from the University of Michigan in Ann Arbor in 1978. I completed a general surgical residency at St. Joseph Mercy Hospital in Ann Arbor from 1978 to 1983, and from 1983 to 1986 I completed a residency in plastic surgery at Duke University Medical Center. In 1986, I joined Duke University Medical Center as an Assistant Professor in the Department of Surgery. In August of 2001, I had to cease surgical practice as a result of injuries suffered in an accident. In November of 2002, I left Duke University Medical Center to start my private clinical practice, which I maintain today, and I resumed surgical practice in December of 2002.

4. I am also a founder of Quill Medical, Inc., which is the assignee of those patents and patent applications on which I am an inventor of barbed tissue connectors and sutures (Exhibit A). Originally founded as Dermagraphics, Inc., Quill Medical, Inc., was formally organized into its present form as a Delaware corporation in December, 2000. I have been a consultant to Quill Medical, Inc., or its predecessors since February 14, 2000.

5. The first time I treated patients using prototype barbed sutures was in June of 1993 at Duke University Medical Center, and I continued to treat patients there using such prototype barbed sutures until the spring of 2001. To my best recollection, I treated 14 patients in 16 procedures during the period between June, 1993 and spring of 2001, using about 35 prototype barbed sutures.

6. For patients treated between June, 1993, and January, 2000, I made prototype barbed sutures by hand in the operating room just prior to treating the patient. These hand-made barbed sutures were prepared by taking commercially available sterile sutures such as Maxon or PDS-II having a curved needle at one end, and cutting a number of barbs into each suture using a sterile scalpel in a sterile field. The cutting was done using clamps to secure the plain suture to a surgical tray. My intention was to cut barbs into the suture at longitudinally spaced intervals to produce a rough helical pattern of barbs along the length of the suture. Multiple barbs facing one end of the suture were cut along a length of the suture, and then the suture was turned slightly on the surgical pan for another series of cuts. The imprecision of the hand-cutting technique, however, likely created a random pattern, and no measurements were taken nor or optical magnification used to determine the uniformity or precision of the cut barbs. Barbs were cut in the suture to obtain a bi-directional arrangement of separate groups of barbs on each suture.

7. Once made, a prototype barbed suture was placed into a patient by first straightening out the curved needle, which was already attached to the suture, in order to insert the needle end and one part of the bi-directional suture into the patient's tissue. To insert the other end of the suture, either a single "eyelet" needle was attached to the free end of the suture and inserted into the patient, or a trocar was passed through the tissue to the entrance point and the remainder of the barbed suture passed into the trocar which was then removed.

8. Beginning in November, 2000, until spring, 2001, several patients were treated with prototype barbed sutures made from commercially available sutures (size 0 PDS from Ethicon) that were cut with a precision, manually-operated, fabrication device designed, constructed by, and obtained under an agreement with, Quill Medical, Inc. (see Exhibit B). This device permitted multiple barbs to be cut at a single time, and allowed the suture to be turned approximately 120 degrees for another series of cuts which were offset longitudinally in order to achieve a helical array in the final prototype barbed suture. Sutures with a bi-directional arrangement of barbs were made with the manual device, and a second needle was swaged onto the free end of the suture. I was also under an obligation of confidentiality with Quill Medical, Inc., during this period as a consequence of my confidentiality and inventions agreement with the Company (see Exhibit C).

9. The patients treated with prototype barbed sutures during the period from June, 1993, until spring, 2001, were treated in a variety of ways to rearrange intact tissue as well as in the closure of cutaneous and deeper wounds. These procedures included: correction of severe ectropion of the ispilateral lower eyelid; shortening of the vertical dimension of the upper lip; symmetrical positioning of the inframammary fold in association with placement of a breast protheses; closure of a wound from an excisional biopsy; and correction of ptotic brows, necks and cheeks.

10. Following each of the surgical procedures described above, I performed at least one follow-up visit with the patient to determine the effectiveness of the prototype barbed sutures and the cosmetic results using such sutures in the different surgical procedures, as well as to observe the durability of the sutures. For a majority of patients, I also had additional follow-up visits to further observe the effectiveness and durability of the barbed suture prototypes. A detailed description for these patients and their treatment follows in the subsequent paragraphs. A summary of the treatment and outcomes for most of these patients is summarized in the attached Exhibit D.

11. In June of 1993, I treated a patient with a deformity attributable to a gun shot wound by supporting the elevation of the left side of the patient's mouth with a prototype barbed

suture using a needle for placing one end of the suture and a trocar for placement of the other end of the suture.

12. In December of 1993, I treated an otherwise healthy male in his early thirties who felt his upper lip covered too much of his upper teeth when he smiled and therefore desired shortening of the vertical dimension of his lip without an external scar. One prototype barbed suture was placed on either side of his upper lip extending vertically from the vermilion of the lip to the base of the nose with the transition point midway along the suture. A modest improvement was seen on the operating table which slowly regressed as I followed his progress over several months. There was no undue tissue reaction from the suture despite the highly mobile nature of this portion of the face.

13. In December of 1993, I treated an otherwise healthy woman in her early twenties who sustained an abrasion of her right malar eminence which extended down into the superficial aspect of the bone. A tissue expander was used inferior to the defect to create new skin; however, the resulting scar contracture caused a severe ectropion of the ipsilateral lower eyelid. This necessitated at least three other procedures to elevate and tighten the lower lid. In three of these procedures, a prototype barbed suture was used to help reduce the tendency of the lower lid to retract about its lateral aspect. The transition point of the prototype barbed suture, at which the barbs change direction, was inferior to the lateral canthal tendon and extended medially under the lower eyelid and laterally toward the temple. To avoid compromise of the zygomatic branches of the facial nerve, the prototype barbed suture was placed very superficially within the attenuated expanded skin. In one instance, this was well tolerated and spontaneously resorbed while in the other, a portion of the suture became exposed and it was removed due to subsequent inflammation. It was felt that the prototype barbed suture contributed to the success of the lower lid reconstruction in each instance.

14. In December of 1993, I also treated a woman with a prototype barbed suture in an attempt to correct a scar on her upper lip.

15. In February of 1994, I treated a child with prototype barbed sutures in an attempt to narrow a web of skin located between her eyes. I placed a prototype barbed suture across the upper bridge of her nose.

16. In August of 1995, I treated a young man with a lower eyelid lesion, using a prototype barbed suture to close the lesion.

17. At approximately the same time as treating the patients described in paragraphs 14-16, above, I also used a prototype barbed suture in an adult to close the wound resulting from a small excisional biopsy of a cutaneous lesion extending down into the subcutaneous tissue. The single prototype barbed suture utilized measured approximately 3 cm in length and was placed in the superficial subcutaneum just deep to the reticular dermis at right angles to the incision with its transition point at the incision. Standard skin sutures were used to close the outer portion of the incision and the wound healed uneventfully. The alternative to the prototype barbed suture would have been an inverted interrupted 3-0 or 4-0 Vicryl suture knotted conventionally.

18. The prototype barbed suture was also utilized in an otherwise healthy woman in her mid-twenties who underwent bilateral breast augmentation utilizing an axillary incision with subpectoral placement of the breast prostheses in May of 1998. Post-operatively, her right inframammary fold was inferiorly displaced and she refused correction with an inframammary incision as was recommended. Accordingly, the axilla was reopened, the prostheses removed and utilizing a fiberoptic scope, prototype barbed sutures were placed percutaneously through the chest wall superficial to the pocket surrounding the prosthesis. The swaged-on needle was introduced first and it, along with the antegrade barbed portion of the prototype barbed suture, were passed through the pocket and into posterior aspect of the capsular scar and periosteum of the rib. The retrograde barbed segment was sheathed in a 16-gauge hypodermic needle which was withdrawn once this portion of the prototype barbed suture entered the anterior chest wall. The transition point therefore lay within the compressed pocket which was effectively closed off at this level by snugging down the anterior chest wall. Four of these prototype barbed sutures were used after which the breast prosthesis was replaced and the axillary wound closed. The inframammary fold was thereby restored to a symmetrical position and the patient recovered uneventfully utilizing compression from her support garments to help maintain the fold at this level. Thus, four prototype barbed sutures effectively closed the inferior portion of the prosthetic pocket without utilizing any conventional sutures.

19. In January of 2000, a prototype barbed suture was utilized in a healthy 34 year-old man with a ptotic brow. One prototype barbed suture was used in a vertical fashion about each side of the forehead extending superiorly from the junction of the middle and lateral third of the eyebrow with its transition point just inferior to the hairline. It was placed at a depth midway between the skin and frontalis muscle. The brow was elevated 6 mm bilaterally and follow-up in 17 months revealed that the lift had relaxed somewhat but that there still appeared to be partial correction of his ptosis. This type of brow lift was used in three other healthy women 34, 58 and 59 years old. One prototype barbed suture was used only on the right side of the two younger patients. Treatment of the 58 and 59 year old women is discussed in paragraph 21 below.

20. In November of 2000, I used for the first time prototype barbed sutures made using the precision, manually-operated, fabrication device from Quill to treat a patient. I treated a 53 year-old patient concerned about aging changes of her neck and upper cheeks by placing prototype barbed sutures in these locations. Her neck was treated as described for the patient in paragraph 22, below, while the transition point for the prototype barbed sutures of this patient's upper cheeks was at the anterior margin of her hairline at the level of the eye.

21. Subsequent to November, 2000, but before spring, 2001, I used prototype barbed sutures placed as described above in paragraph 19, but in the 58 year-old patient in that it was placed deep to the frontalis muscle, in an attempt to minimize its palpability. While both patients tolerated the prototype barbed suture placement well post-operatively, the older patient had recurrence of the brow ptosis within two months which may have been due to its depth. She had noticed some pulling and 'snapping' sensations when she raised and lowered her right eyebrow. The location of the prototype barbed suture in the loose plane over which the forehead moves may have deflected the barbs causing these feelings which subsided in 4-6 weeks. The 59 year-old patient's ptotic brows were lifted with two prototype barbed sutures on each side combined with a chemical peel of her forehead. Ongoing follow-up shows no untoward suture reaction and residual correction at two months.

22. Also subsequent to November, 2000, but before spring, 2001, I used a prototype barbed suture placed in an otherwise healthy 60 year-old woman concerned about laxity of the skin of her neck and lower cheeks. The sutures were placed in a linear fashion bilaterally in each of these areas with the transition point of the suture overlying the sternomastoid muscle and posterior cheek, respectively. The portion of the prototype barbed suture posterior to this point was approximately 3 cm while the portion of the barbed suture anterior to this point measured approximately 8 cm.

23. All of the prototype barbed sutures placed in the cheeks and necks of patients described in paragraphs 22 and 20 were in the subcutaneous plane and all resulted in excellent immediate correction of the skin laxity in these regions. However, the ends of the sutures in each patient's neck and those in the younger patient's upper cheeks, became prominent about their medial ends in the period from one to three weeks post placement. These were subsequently removed under local anesthesia and the portion of the suture that was recovered contained barbs in one direction only suggesting that they broke at their transition point. Evaluation of extra sutures manufactured simultaneously with those placed in these patients revealed that the barbs cut at opposing directions overlapped at the transition point, thereby weakening the suture at this juncture. The cutting blades of the fabrication device were adjusted to correct this problem and the prototype barbed sutures above the neck and upper cheeks of the younger patient were replaced and well tolerated with improvement lasting at least three months post-operatively.

24. The patients described above were generally informed that they were being treated with conventional sutures modified by barbing of the suture filament. The surgical assistants in the operating room also had general knowledge of the prototype barbed sutures. Reconstructive patients were usually under general anesthesia, whereas the patients being treated cosmetically were under either general or local anesthesia depending on the case. All patient medical records were under obligations of confidentiality pursuant to the policies of Duke University Medical Center.

25. A summary of my experience with prototype barbed sutures as set forth above was submitted by Quill Medical, Inc., to the Food and Drug Administration as part of a 510(k) application for clearance of a "PDS II Synthetic Absorbable Surgical Suture." This

510(k) application was submitted on October 16, 2001, and was decided on October 26, 2004. A copy of this summary is attached as Exhibit E.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Gregory Ruff MD

Date: August 19, 2005

EXHIBIT A

List of Patents and Pending Patent Applications Naming Gregory L. Ruff as an Inventor

1. US 5,342,376 – Inserting Device for a Barbed Tissue Connector
2. US 6,241,747 – Barbed Bodily Tissue Connector
3. US 6,599,310 – Suture Method
4. US 6,773,450 – Suture Anchor and Method
5. US 2005/0033367A1 – Suture Anchor and Method
6. US 2004/0088003A1 – Barbed Suture in Combination with Surgical Needle
7. US 2004/0030354A1 – Suture Anchor and Method
8. US 2003/0014077A1 – Suture Method
9. US 2004/0093028A1 – Barbed Bodily Tissue Connector
10. US 2004/0060410A1 – Barbed Sutures
11. US 2004/0060409A1 – Barb Configurations for Barbed Sutures
12. US 2003/0074023A1 – Suture Method

EXHIBIT B

CONFIDENTIAL

Quill Medical, Inc.

November 8, 2000

Gregory L. Ruff, M.D.
201 Longwood Drive
Chapel Hill, NC 27514

Dear Greg:

This Letter Agreement sets forth the mutual understanding regarding the terms of the agreement between Gregory L. Ruff ("**Ruff**") and Quill Medical, Inc. (the "**Company**") regarding the Company permitting Ruff to use the "**Fabrication Device**" (as defined below) during operating room procedures and the agreement of Ruff to indemnify, defend and hold harmless the Company for any liability incurred by the Company in connection with Ruff's use of the Product (as defined below).

WHEREAS, the Company has created a "**Fabrication Device**" for fabricating barbed sutures, which Ruff desires to use in operating room procedures. The Company hereby grants Ruff a license to use the Fabrication Device in operating room procedures to be performed from time to time.

In consideration for the Company granting Ruff the right to use the Fabrication Device in the operating room procedures, Ruff agrees to indemnify, defend and hold harmless the Company (and its respective officers, directors, employees, agents and affiliates) from and against any third-party claim, suit, action or proceeding brought against the Company that is based upon or arises out of the use of the Fabrication Device by Ruff in the operating room procedures, and from and against any and all liabilities, losses, costs, damages, and expenses (including reasonable attorneys' fees) associated with any such claims or actions.

This Letter Agreement constitutes the entire agreement between the Company and Ruff and supersedes any prior understandings, agreements, or representations by or among Ruff and the Company, written or oral, to the extent they relate in any way to the subject matter hereof.

This Letter Agreement will be governed by and construed in accordance with the laws of the State of North Carolina without giving effect to any choice or conflict of law provision or rule (whether of the State of North Carolina or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of North Carolina.

If the foregoing is acceptable, please so indicate by signing and dating this Letter Agreement below and return an executed original of this Letter Agreement to the undersigned. This Letter Agreement, when executed by Ruff and returned to the Company, will constitute a binding agreement between Ruff and the Company that will be enforceable in accordance with its terms and that cannot be modified, amended, or terminated (except as provided herein) other than by a written instrument executed and delivered on behalf of Ruff and the Company.

Very truly yours,

QUILL MEDICAL, INC.

By: _____
Matthew A. Megaro
President

ACKNOWLEDGED AND AGREED:

_____
Gregory L. Ruff

Date: 11/10/00

EXHIBIT C

CONFIDENTIAL

CONFIDENTIALITY, INVENTIONS AND NON-COMPETITION AGREEMENT

THIS CONFIDENTIALITY, INVENTIONS AND NON-COMPETITION AGREEMENT (this "Agreement") is effective as of February 14, 2000 by and between Quill Medical, Inc., a North Carolina corporation, and its affiliates, subsidiaries, successors and assigns (collectively the "Company"), and the undersigned, an individual serving as *[check the appropriate space and initial]*

	Initials
____ an employee of Company; or	_____
✓ an independent contractor engaged by Company	GL

STATEMENT OF PURPOSE

Company's business includes the use and development of certain Proprietary Information (as defined below). Company's business success and competitive position in the industry are dependent on keeping Proprietary Information confidential. The undersigned is being engaged by Company and may use Proprietary Information in the performance of the undersigned's duties. As a condition to Company's engagement of the undersigned and making Proprietary Information available to the undersigned, the undersigned has agreed to execute this Agreement and to keep all such Proprietary Information confidential.

IN CONSIDERATION of the disclosure by Company to the undersigned of any Proprietary Information, and for other good and valuable consideration, the undersigned agrees to the following:

1. "Proprietary Information" Defined. For purposes of this Agreement, "Proprietary Information" is information (whether in written or other form or whether or not patentable or protectable by copyright) that has been created, discovered, developed or has otherwise become known to Company, and that has a commercial value in the business of Company. Proprietary Information includes, but is not limited to, all inventions, processes, ideas, data, computer programs, developments, designs, marketing plans, customer lists, budgets, projections, cost analyses, acquisition candidates and other information owned by Company that is not public information.

2. Nondisclosure of Proprietary Information.

2.1 The undersigned recognizes that Proprietary Information is the sole property of Company. During and after the undersigned's engagement by Company, the undersigned shall keep in the strictest of confidence and trust all Proprietary Information and shall not disclose or use any Proprietary Information except as required by law or permitted in writing by Company.

2.2 The undersigned shall not use or disclose to Company, or assist in the disclosure to Company of, confidential information belonging to any third parties, including any prior employer(s).

3. Return of Documents. Upon the termination of the undersigned's engagement by Company for any reason, the termination of the undersigned's access to Proprietary Information or upon the earlier request of Company, the undersigned shall return to Company all materials belonging to Company, whether kept at the undersigned's business office, personal residence or otherwise, including all materials containing or relating to any Proprietary Information in any written or tangible form that the undersigned may have in his or her possession or control. After returning the materials described in the preceding sentence to Company, the undersigned shall not retain any copies of any such materials.

4. Ownership of Work Product.

4.1 All inventions, discoveries, computer programs, developments, designs, improvements, formulae, processes, techniques, programs, know-how, data or other information of possible technical or commercial importance relating to Company's business or Company's anticipated business or based on, derived from or relating to any Proprietary Information (collectively, "Work Product") shall be the sole property of Company. All Work Product made or conceived by the undersigned, solely or jointly, during the undersigned's engagement by Company shall be deemed "works made for hire," as that term is defined in Section 101 of the U.S. Copyright Act of 1976, as amended.

4.2 If, for any reason, any Work Product does not qualify as work made for hire, the undersigned shall assign and does hereby assign to Company all such Work Product. The undersigned shall assist Company, at Company's expense, in every necessary way to obtain or enforce any patents, copyrights or other proprietary rights relating to the Work Product and to execute all documents necessary to give to Company full legal ownership to such Work Product, and the undersigned shall continue such assistance after the termination of his or her engagement by Company.

4.3 During the undersigned's engagement by Company, the undersigned shall report promptly to Company all Work Product made or conceived by the undersigned, solely or jointly.

4.4 The undersigned hereby designates and appoints Company and its duly authorized officers and agents as its agents and attorneys-in-fact to execute and file any certificates, applications or documents and to do all of their lawful acts necessary to protect Company's rights in the Work Product. The undersigned expressly acknowledges that the foregoing power of attorney is coupled with an interest and is therefore irrevocable and shall survive his or her death or incompetency and the termination of his or her engagement by Company.

4.5 The undersigned hereby represents and warrants that the undersigned has fully disclosed to Company on Schedule A attached hereto any idea, invention, discovery or process relating to the Company's business which, prior to his or her engagement with Company, the

undersigned conceived of or developed wholly or in part, and is to be excluded from the scope of this Agreement.

4.6 Notwithstanding anything in this Agreement to the contrary, the obligation of the undersigned to assign or offer to assign his or her rights in an invention to Company shall not extend or apply to an invention that the undersigned developed entirely on his or her own time without using Company equipment, supplies, facility or trade secret information unless such invention (a) relates to Company's business or actual or demonstrably anticipated research or development, or (b) results from any work performed by the undersigned for Company. The undersigned shall bear the burden of proof in establishing that his or her invention qualifies for exclusion under this Section 4.6.

5. Covenant Not To Compete.

5.1 It is recognized and understood by the parties hereto that the undersigned, through his or her association with Company, has and shall acquire a considerable amount of knowledge and goodwill with respect to the business of Company, which knowledge and goodwill are extremely valuable to Company and which would be extremely detrimental to Company if used by the undersigned to compete with Company. It is, therefore, understood and agreed by the parties hereto that, because of the nature of the business of Company, it is necessary to afford fair protection to Company from such unfair competition by the undersigned.

5.2 Consequently, as material inducement to engage the undersigned, the undersigned covenants and agrees that at any time while engaged by Company and for a period of one (1) year following his or her termination, he or she will not, directly or indirectly, with or through any family member or former director, officer or employee of Company, or acting alone or as a director, employee, agent, consultant, member of a partnership, firm, corporation or other entity or as a holder of or investor in as much as 5% of any security of any class of any corporation or other business entity:

(a) engage anywhere in the Noncompetition Area (as defined below) in any business related to the business then being actively pursued or reasonably anticipated to be pursued by Company at the time of such termination; or

(b) interfere with, or seek to interfere with, the relationship between Company and any affiliate of Company with the following: (a) any of the employees of such entities; (b) any of the customers of such entities then existing or existing at any time within two (2) years prior to termination of the undersigned's engagement by Company; or (c) any of the suppliers of such entities then existing or existing at any time within two (2) years prior to termination of the undersigned's engagement by Company; or

(c) solicit to hire or hire any person who was an employee of Company or an affiliate of Company within the prior six (6) months.

5.3 For the purpose of this Agreement, the "Noncompetition Area" shall be (i) the entire world; (ii) the United States of America; (iii) each state in which Company does business

or did business at any time within two (2) years prior to the termination of the undersigned's engagement by Company; (iv) the States of Maryland, Virginia, North Carolina, South Carolina and Georgia; and (v) the State of North Carolina. If a court of competent jurisdiction determines that the Noncompetition Area described above in subparagraph (i) is too restrictive, then the parties agree that the Noncompetition Area shall be the area specified in subparagraph (ii). If a court of competent jurisdiction determines that the Noncompetition Area as set forth in subparagraphs (i) and (ii) above are too restrictive, then the parties agree the Noncompetition Area shall be reduced to the area specified in each of the following subsections and in the following order until the court determines an acceptable geographic area: subparagraphs (iii), (iv), or (v). If the court determines that all of the areas mentioned above are too restrictive, then the parties agree that the court may reduce or limit the area to enable the intent of this Section to be enforced in the largest acceptable area.

5.4 The parties hereto agree that in the event that the length of time set forth in Section 5.2 is deemed too restrictive in any court proceeding, that the court may reduce such restrictions to those which it deems reasonable under the circumstances.

5.5 The undersigned agrees and acknowledges that Company does not have an adequate remedy at law for the breach or threatened breach by him or her of this Section 5 and agrees that Company may, in addition to the other remedies which may be available to it under this Agreement, file suit in equity to enjoin the undersigned from such breach or threatened breach.

6. Independent Contractor Status.

6.1 If the undersigned has so indicated by initialing "independent contractor" above, the undersigned acknowledges and agrees that the undersigned shall be treated as an independent contractor of Company, and not as an employee, agent or authorized representative of Company. Although the undersigned will receive generalized instruction from Company as to the performance of services, Company shall not control or supervise the specific methods to be used or the sequence of tasks to be performed in connection with the undersigned's duties. The acts of the undersigned shall not constitute the acts of Company, and the undersigned shall not represent to any third party that the undersigned has any express or implied authority to bind Company to any contract, agreement or obligation.

6.2 If the undersigned has so indicated by initialing "independent contractor" above, the undersigned further acknowledges that the undersigned will be treated by Company as an independent contractor for federal and state income tax, social security tax and state unemployment tax purposes. Accordingly, Company shall not withhold from any consideration paid to the undersigned any amounts for federal or state income taxes or social security (FICA) for the undersigned. The undersigned shall indemnify and hold harmless Company from and against any damage, claim, assessment, interest, charge, cost or expense (including attorneys' fees) or penalty incurred by or charged to Company as a result of any claim, cause of action or assessment by any federal or state government or agency for any nonpayment or underpayment by the undersigned of any tax.

7. Miscellaneous.

7.1 The parties acknowledge that this Agreement does not constitute and shall not be deemed an agreement of employment for any specific duration, even if the undersigned individual is an employee of Company.

7.2 Failure to insist upon strict compliance with any provision of this Agreement shall not be deemed a waiver of such provision or of any other provision in the Agreement.

7.3 This Agreement shall be subject to and governed by the laws of the Sate of North Carolina, without regard to the conflicts-of-law rules of such State.

7.4 This Agreement contains the entire understanding between the parties with respect to the subject matter hereof and supersedes all prior or contemporary agreements or understandings, whether written or oral, with respect thereto. This Agreement may not be modified or amended except by an agreement in writing signed by both parties.

7.5 Nothing in this Agreement or the obligations or relationship contemplated hereby shall be deemed to create a relationship of partners, joint ventures, associates or principal-and-agent between Company and the undersigned.

7.6 Arbitration and Equitable Relief.

a. Arbitration. Except as provided in Section 7.6(b) below, the undersigned agrees that any dispute or controversy arising out of, relating to, or concerning any interpretation, construction, performance or breach of this Agreement, shall be settled by arbitration to be held in accordance with (a) the Employment Dispute Resolution Rules then in effect (if the undersigned is an employee of Company) or (b) the Commercial Rules then in effect (if the undersigned is an independent contractor) of the American Arbitration Association. The arbitrator may grant injunctions or other relief in such dispute or controversy. The decision of the arbitrator shall be final, conclusive and binding on the parties to the arbitration. Judgment may be entered on the arbitrator's decision in any court having jurisdiction. Company and the undersigned shall each pay their own respective attorneys' fees and one-half of the costs and expenses of such arbitration (provided, however, that if the arbitrator finds that the arbitration action was brought or defended other than in good faith and with a reasonable basis in fact, the non-prevailing party shall pay all such costs and expenses of arbitration and the other party's attorneys' fees and expenses).

This arbitration clause constitutes a waiver of the undersigned's right to a jury trial and relates to the resolution of all disputes relating to all aspects of the employer/employee or independent contractor relationship (except as provided in Section 7.6(b) below), including, but not limited to, the following claims.

(i) Any and all claims for wrongful discharge of employment; breach of contract, both express and implied; breach of the covenant of good faith and fair dealing,

both express and implied; negligent or intentional infliction of emotional distress; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; and defamation;

(ii) Any and all claims for violation of any federal, state or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964, the Civil Rights Act of 1991, the Age Discrimination in Employment Act of 1967, the Americans with Disabilities Act of 1990, the Fair Labor Standards Act, and Labor Code Section 201, *et seq.*;

(iii) Any and all claims arising out of any other laws and regulations relating to employment or employment discrimination.

b. Equitable Remedies. The undersigned agrees that it would be impossible or inadequate to measure and calculate Company's damages from any breach of the Agreement. Accordingly, the undersigned agrees that if the undersigned breaches any of such sections, Company will have available, in addition to any other right or remedy available, the right to obtain an injunction from a court of competent jurisdiction restraining such breach or threatened breach and to obtain specific performance of any such provision of this Agreement. The undersigned further agrees that no bond or other security shall be required in obtaining such equitable relief and the undersigned hereby consents to the issuance of such injunction and to the ordering of specific performance.

c. Consideration. The undersigned understands that each party's promise to resolve claims by arbitration in accordance with the provisions of this Agreement, rather than through the courts, is consideration for the other party's like promise. The undersigned further understands that the undersigned is offered employment/engagement in consideration of the undersigned's promise to arbitrate claims.

EXHIBIT C

CONFIDENTIAL

IN WITNESS WHEREOF, the parties have executed this Agreement to be effective as of the date set forth above.

QUILL MEDICAL, INC.

By: Merrill M Mason

Name: Merrill M. Mason

Title: Secretary

Date: 2-14, 2000

Gregory L Ruff

Signature of Employee or Independent Contractor

Gregory H. Ruff

Printed Name of Employee or Independent Contractor

Date: 2-14, 2000

CONFIDENTIAL

SCHEDULE A

The following items are inventions, ideas, computer software programs or other equipment or technology not covered by Section 4 of this Agreement, which the undersigned conceived of or developed, wholly or in part, prior to his or her engagement with Company and shall be excluded from the scope of this Agreement.

If the undersigned has no such items to disclose, write "NONE" on this line:
None.

Description of Items: (if applicable)

Title on Document	Date on Document	Name of Witness on Document

QUILL MEDICAL, INC.

By: Merrill M Mason (SEAL)
Its: Secretary

Gregory L Ruff (SEAL)
Printed Name: Gregory L. Ruff

2-14-00
Date

H&M: 57934.1

EXHIBIT D

Quill Medical Custom Device Experience
1993 - 2001

Procedure	Patient Age	Gender	Site	Number of Quill Sutures Used	Duration of Follow-up	Adverse Reaction
Tissue Sculpting	50's	M	L cheek	1	> 3 mos.	-
	20's	F	R lower eyelid	1	>3 mos.	-
	20's	F	R lower eyelid	1	<1 mo.	Exposed
	30's	M	L, R upper lip	2	4 mos.	-
	34	M	L, R brow	2	17 mos.	-
	34	F	R brow	1	3 mos.	-
	58	F	R brow	1	2 mos.	-
	59	F	L, R brow	4	2 mos.	-
	60	F	L, R neck L, R lower cheek	2 2	<1 mo. 3 mos.	Broken -
	53	F	L, R neck L, R upper cheek	2 2	<1 mo. <1 mo.	Broken Broken
	53	F	L, R neck L, R upper cheek	2 2	8 mos. 8 mos.	- -

Procedure	Patient Age	Gender	Site	Number of Quill Sutures Used	Duration of Follow-up	Adverse Reaction
Wound Closure	20's	F	R breast	4	3 mos.	-
	40's?	M?	Arm	1	<1 mo.	

Summary:
11 Patients
12 Procedures
30 Quill Sutures Used
77% (23/30) Successful
23% (7/30) Failed

Quill Medical
Custom Device Experience

Gregory Ruff, MD of Duke University Medical Center designed the Quill Medical suture concept in response to specific plastic and reconstructive surgical needs for specific patients presenting to Dr. Ruff's practice beginning in early 1993.

Quill sutures were made by hand from1993 until 2000 utilizing Ethicon PDS II suture sizes 0 or 1. Dr. Ruff cut the initial Quill sutures during surgery with a #15 scalpel blade into the Ethicon PDS II sutures that were clamped over a flat-bottomed basin in a sterile field. Initially the barb configuration was designed as a spiral array around the long axis of the suture though imprecision of the hand-cutting technique ultimately created a random pattern.

During 2000, Quill Medical sutures were created prior to surgery by cutting barbs into Ethicon PDS II size 0 sutures using a prototype machine. The barbed sutures' ends were swaged with a second needle after cutting the barbs. The barbed needled sutures were then resterilized using a standard ETO sterilization cycle.

The details of Dr. Ruff's custom device experience with custom Quill Medical suture are presented in Tab 1.

In summary, twenty-nine (29) custom Quill sutures were used in 10 patients undergoing twelve (12) Plastic and Reconstructive surgical procedures over a period about 9 years. The custom Quill sutures have been used in a variety of ways to rearrange intact tissue as well as in the closure of cutaneous and deeper wounds. Quill sutures were successful in 22/29 (76%) uses and failed in 7/29 (24%) uses. Exposure of the barbed suture was the only complication which troubled any patient. This occurred once in very thin skin into which Quill suture was placed very superficially and later in two patients in whom the manufacturing process was thought to have weakened the Quill suture at its transition point resulting in breakage thereof with post-operative animation of the face and neck. This custom Quill suture experience suggests that Quill sutures will be well tolerated when placed deep to the reticular dermis and manufactured as designed.

Quill Medical Suture Custom Device Experience
1993 – 2000

Patients	10
Procedures	12
Quill Sutures Used	29
Successful	76% (22/29)
Failed	24% (7/29)